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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,866

07/22/2003

Dennis M. Brown

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03/03/2008

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

03/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/625,866	Applicant(s) BROWN, DENNIS M.	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

Applicant's amendment filed January 1, 2008 has been received and entered into the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

I Claims 1, 4-9 and 13-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. (U.S. Patent No. 3,793,454) in view of D'Amato (U.S. Patent No. 5,712,291), Kawai et al. (Cancer Letters, 171 (2001) 201-207) and Powell II, (Journal of Pharmaceutical Sciences article), each of record, for the reasons of record as set forth in the previous Office action dated July 5, 2007, which reasons are here incorporated by reference.

Applicant's remarks have been carefully considered, but fail to persuade the Examiner of error in maintaining the rejection.

In traversing the present rejection, Applicants have advanced and relied heavily on the concepts of inherency. It is recognized that the Examiner did mention inherency in his previous grounds of rejecting the claims. However, the concept of inherency is not the bedrock for rejecting the present claims. Indeed, the broader, instructive disclosure of Powell which makes clear that the active disclosed can be used for the treatment of leukemia is more than sufficient to establish a *prima facie* case of obviousness. Further, Powell et al. clearly discloses sufficient information that one of ordinary skill in the art would have recognized the clinical usefulness of the invention of Powell in treating leukemia. Applicant's mere supposition cannot detract from this.

The above and those reasons set forth in the previous Office action dated July 5, 2005 clearly establish a *prima facie* case of obviousness which Applicant has not overcome by either persuasive argument or a showing of unexpected results.

Accordingly, the Examiner will maintain his position that the claimed subject matter would have been obvious under 35 U.S.C. § 103(c).

II Claims 1, 4-9 and 13-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. (U.S. Patent No. 3,793,454) in view of D'Amato (U.S. Patent No. 5,712,291), Kawai et al. (Cancer Letters, 171 (2001) 201-207) and Powell II, (Journal of Pharmaceutical Sciences article), each of record, for the reasons of record as set forth in the previous Office action dated July 5, 2007, which reasons are here incorporated by reference.

Applicant's remarks have been carefully considered, but fail to persuade the Examiner of error in maintaining the rejection.

In traversing the present rejection, Applicants have offered that the property which the Examiner indicated as being undeniable, does not so occur, but only, maybe, possibly. The property of interest is angiogenesis, i.e., the growth of new blood vessels. Such growth is deemed inherent in every living being, especially the claimed living beings which are merely "a host". Contrary to Applicant's opinion, there is no "probability" because in a host, there must be growths of blood vessels and thus a necessary event.

Applicants have further advanced that they have discovered a new use for an old structure, such use being inhibition of angiogenesis, (note page 8 of Applicant's remarks). The prior art, however, discloses administering the active agent as in the present claims, (i.e., a cephalotaxine), to a host. Such use, however, must be deemed inherent as the prior art teaches

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such administration and the host to whom it is administered has vascular which is necessarily subject to angiogenesis. Thus, this remark of Applicant is not impressive.

At page 8 of their response, Applicant has advanced that “[o]bviousness cannot be predicated on what is not known at the time an invention was made, even if the inherency of a certain feature is later established”, (remarks at page 8, second full paragraph).

In response, the Examiner notes that inherency of the feature of the active to inhibit angiogenesis need not be later established; indeed it need not even be recognized by the skilled artisan, (There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003), see MPEP 2112(II).)

For the above reasons, the claims are deemed to remain properly rejected.

None of the claims are currently in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

February 21, 2008

/Raymond J Henley III/
Primary Examiner, Art Unit 1614

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/625,866	BROWN, DENNIS M.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	